

109TH CONGRESS
1ST SESSION

S. 470

To amend the Public Health Service Act to expand the clinical trials drug data bank.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2005

Mr. DODD (for himself, Mr. GRASSLEY, Mr. JOHNSON, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to expand the clinical trials drug data bank.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fair Access to Clinical
5 Trials Act of 2005” or the “FACT Act”.

6 **SEC. 2. PURPOSE.**

7 It is the purpose of this Act—

8 (1) to create a publicly accessible national data
9 bank of clinical trial information comprised of a clin-

1 ical trial registry and a clinical trial results data-
 2 base;

3 (2) to foster transparency and accountability in
 4 health-related intervention research and develop-
 5 ment;

6 (3) to maintain a clinical trial registry acces-
 7 sible to patients and health care practitioners seek-
 8 ing information related to ongoing clinical trials for
 9 serious or life-threatening diseases and conditions;
 10 and

11 (4) to establish a clinical trials results database
 12 of all publicly and privately funded clinical trial re-
 13 sults regardless of outcome, that is accessible to the
 14 scientific community, health care practitioners, and
 15 members of the public.

16 **SEC. 3. CLINICAL TRIALS DATA BANK.**

17 (a) IN GENERAL.—Section 402(j) of the Public
 18 Health Service Act (42 U.S.C. 282(j)) is amended—

19 (1) in paragraph (1)(A), by striking “for drugs
 20 for serious or life-threatening diseases and condi-
 21 tions”;

22 (2) in paragraph (2), by striking “available to
 23 individuals with serious” and all that follows
 24 through the period and inserting “accessible to pa-
 25 tients, other members of the public, health care

1 practitioners, researchers and the scientific commu-
 2 nity. In making information about clinical trials pub-
 3 licly available, the Secretary shall seek to be as time-
 4 ly and transparent as possible.”;

5 (3) by redesignating paragraphs (4) and (5), as
 6 paragraphs (8) and (9), respectively;

7 (4) by striking paragraph (3) and inserting the
 8 following:

9 “(3) The data bank shall include the following:

10 “(A)(i) A registry of clinical trials (in this sub-
 11 paragraph referred to as the ‘registry’) of health-re-
 12 lated interventions (whether federally or privately
 13 funded).

14 “(ii) The registry shall include information for
 15 all clinical trials conducted to test the safety or ef-
 16 fectiveness (including comparative effectiveness) of
 17 any drug, biological product, or device (including
 18 those drugs, biological products, or devices approved
 19 or cleared by the Secretary) intended to treat serious
 20 or life-threatening diseases and conditions, except
 21 those Phase I clinical trials conducted to test solely
 22 the safety of an unapproved drug or unlicensed bio-
 23 logical product, or pilot or feasibility studies con-
 24 ducted to confirm the design and operating speci-
 25 fications of an unapproved or not yet cleared med-

1 ical device. For purposes of this section, Phase I
2 clinical trials are trials described in section
3 313.12(a) of title 21, Code of Federal Regulations
4 (or any successor regulations).

5 “(iii) The registry may include information
6 for—

7 “(I) Phase I clinical trials conducted to
8 test solely the safety of an unapproved drug or
9 unlicensed biological product, or pilot or feasi-
10 bility studies conducted to confirm the design
11 and operating specifications of an unapproved
12 or not yet cleared medical device with the con-
13 sent of the responsible person; and

14 “(II) clinical trials of other health-related
15 interventions with the consent of the responsible
16 person.

17 “(iv) The information to be included in the reg-
18 istry under this subparagraph shall include the fol-
19 lowing:

20 “(I) Descriptive information, including a
21 brief title, trial description in lay terminology,
22 trial phase, trial type, trial purpose, description
23 of the primary and secondary clinical outcome
24 measures to be examined in the trial, the time
25 at which the outcome measures will be assessed,

1 and the dates and details of any revisions to
2 such outcomes.

3 “(II) Recruitment information, including
4 eligibility and exclusion criteria, a description of
5 whether, and through what procedure, the man-
6 ufacturer or sponsor of the investigation of a
7 new drug will respond to requests for protocol
8 exception, with appropriate safeguards, for sin-
9 gle-patient and expanded protocol use of the
10 new drug, particularly in children, a statement
11 as to whether the trial is closed to enrollment
12 of new patients, overall trial status, individual
13 site status, and estimated completion date. For
14 purposes of this section the term ‘completion
15 date’ means the date of the last visit by sub-
16 jects in the trial for the outcomes described in
17 subclause (I).

18 “(III) Location and contact information,
19 including the identity of the responsible person.

20 “(IV) Administrative data, including the
21 study sponsor and the study funding source.

22 “(V) Information pertaining to experi-
23 mental treatments for serious or life threat-
24 ening diseases and conditions (whether federally
25 or privately funded) that may be available—

1 “(aa) under a treatment investiga-
2 tional new drug application that has been
3 submitted to the Secretary under section
4 360bbb(c) of title 21, Code of Federal
5 Regulations; or

6 “(bb) as a Group C cancer drug (as
7 defined by the National Cancer Institute).

8 “(B)(i) A clinical trials results database (in this
9 subparagraph referred to as the ‘database’) of
10 health-related interventions (whether federally or
11 privately funded).

12 “(ii) The database shall include information for
13 all clinical trials conducted to test the safety or ef-
14 fectiveness (including comparative effectiveness) of
15 any drug, biological product, or device (including
16 those drugs, biological products, or devices approved
17 or cleared by the Secretary), except those Phase I
18 clinical trials conducted to test solely the safety of
19 an unapproved drug or unlicensed biological product,
20 or pilot or feasibility studies conducted to confirm
21 the design and operating specifications of an unap-
22 proved or not yet cleared medical device.

23 “(iii) The database may include information
24 for—

1 “(I) Phase I clinical trials conducted to
 2 test solely the safety of an unapproved drug or
 3 unlicensed biological product, or pilot or feasi-
 4 bility studies conducted to confirm the design
 5 and operating specifications of an unapproved
 6 or not yet cleared medical device with the con-
 7 sent of the responsible person; and

8 “(II) clinical trials of other health-related
 9 interventions with the consent of the responsible
 10 person.

11 “(iv) The information to be included in the
 12 database under this subparagraph shall include the
 13 following:

14 “(I) Descriptive information, including—

15 “(aa) a brief title;

16 “(bb) the drug, biological product or
 17 device to be tested;

18 “(cc) a trial description in lay termi-
 19 nology;

20 “(dd) the trial phase;

21 “(ee) the trial type;

22 “(ff) the trial purpose;

23 “(gg) the estimated completion date
 24 for the trial; and

1 “(hh) the study sponsor and the study
2 funding source.

3 “(II) A description of the primary and sec-
4 ondary clinical outcome measures to be exam-
5 ined in the trial, the time at which the outcome
6 measures will be assessed, and the dates and
7 details of any revisions to such outcomes.

8 “(III) The actual completion date of the
9 trial and the reasons for any difference from
10 such actual date and the estimated completion
11 date submitted pursuant to subclause (I)(hh).
12 If the trial is not completed, the termination
13 date and reasons for such termination.

14 “(IV) A summary of the results of the trial
15 in a standard, non-promotional summary for-
16 mat (such as ICHE3 template form), including
17 the trial design and methodology, results of the
18 primary and secondary outcome measures as
19 described in subclause (II), summary data ta-
20 bles with respect to the primary and secondary
21 outcome measures, including information on the
22 statistical significance or lack thereof of such
23 results.

24 “(V) Safety data concerning the trial (in-
25 cluding a summary of all adverse events speci-

1 fying the number and type of such events, data
2 on prespecified adverse events, data on serious
3 adverse events, and data on overall deaths).

4 “(VI) Any publications in peer reviewed
5 journals relating to the trial. If the trial results
6 are published in a peer reviewed journal, the
7 database shall include a citation to and, when
8 available, a link to the journal article.

9 “(VII) A description of the process used to
10 review the results of the trial, including a state-
11 ment about whether the results have been peer
12 reviewed by reviewers independent of the trial
13 sponsor.

14 “(VIII) If the trial addresses the safety,
15 effectiveness, or benefit of a use not described
16 in the approved labeling for the drug, biological
17 product, or device, a statement, as appropriate,
18 displayed prominently at the beginning of the
19 data in the registry with respect to the trial,
20 that the Food and Drug Administration—

21 “(aa) is currently reviewing an appli-
22 cation for approval of such use to deter-
23 mine whether the use is safe and effective;

24 “(bb) has disapproved an application
25 for approval of such use;

1 “(cc) has reviewed an application for
2 approval of such use but the application
3 was withdrawn prior to approval or dis-
4 approval; or

5 “(dd) has not reviewed or approved
6 such use as safe and effective.

7 “(IX) If data from the trial has not been
8 submitted to the Food and Drug Administra-
9 tion, an explanation of why it has not been sub-
10 mitted.

11 “(X) A description of the protocol used in
12 such trial to the extent necessary to evaluate
13 the results of such trial.

14 “(4)(A) Not later than 90 days after the date of the
15 completion of the review by the Food and Drug Adminis-
16 tration of information submitted by a sponsor in support
17 of a new drug application, or a supplemental new drug
18 application, whether or not approved by the Food and
19 Drug Administration, the Commissioner of Food and
20 Drugs shall make available to the public the full reviews
21 conducted by the Administration of such application.

22 “(B) Not later than 90 days after the date of the
23 completion of a written consultation on a drug concerning
24 the drug’s safety conducted by the Office of Drug Safety,
25 regardless of whether initiated by such Office or outside

1 of the Office, the Commissioner of Food and Drugs shall
2 make available to the public a copy of such consultation
3 in full.

4 “(C) Nothing in this paragraph shall be construed to
5 alter or amend section 301(j) or section 1905 of title 18,
6 United States Code.

7 “(D) This paragraph shall supersede section 552 of
8 title 5, United States Code.

9 “(5) The information described in subparagraphs (A)
10 and (B) of paragraph (3) shall be in a format that can
11 be readily accessed and understood by members of the
12 general public, including patients seeking to enroll as sub-
13 jects in clinical trials.

14 “(6) The Secretary shall assign each clinical trial a
15 unique identifier to be included in the registry and in the
16 database described in subparagraphs (A) and (B) of para-
17 graph (3). To the extent practicable, this identifier shall
18 be consistent with other internationally recognized and
19 used identifiers.

20 “(7) To the extent practicable, the Secretary shall en-
21 sure that where the same information is required for the
22 registry and the database described in subparagraphs (A)
23 and (B) of paragraph (3), a process exists to allow the
24 responsible person to make only one submission.”; and

25 (5) by adding at the end the following:

1 “(10) In this section, the term ‘clinical trial’ with re-
 2 spect to the registry and the database described in sub-
 3 paragraphs (A) and (B) of paragraph (3) means a re-
 4 search study in human volunteers to answer specific health
 5 questions, including treatment trials, prevention trials, di-
 6 agnostic trials, screening trials, and quality of life trials.”.

7 (b) ACTIONS OF SECRETARY REGARDING CLINICAL
 8 TRIALS.—Section 402 of the Public Health Service Act
 9 (42 U.S.C. 282) is amended—

10 (1) by redesignating subsections (k) and (l) as
 11 subsections (q) and (r), respectively; and

12 (2) by inserting after subsection (j), the fol-
 13 lowing:

14 “(k) FEDERALLY SUPPORTED TRIALS.—

15 “(1) ALL FEDERALLY SUPPORTED TRIALS.—

16 With respect to any clinical trial described in sub-
 17 section (j)(3)(B) that is supported solely by a grant,
 18 contract, or cooperative agreement awarded by the
 19 Secretary, the principal investigator of such trial
 20 shall, not later than the date specified in paragraph
 21 (2), submit to the Secretary—

22 “(A) the information described in sub-
 23 clauses (II) through (X) of subsection
 24 (j)(3)(B)(iv), and with respect to clinical trials
 25 in progress on the date of enactment of the

1 FACT Act, the information described in sub-
2 clause (I) of subsection (j)(3)(B)(iv); or

3 “(B) a statement containing information
4 sufficient to demonstrate to the Secretary that
5 the information described in subparagraph (A)
6 cannot reasonably be submitted, along with an
7 estimated date of submission of the information
8 described in such subparagraph.

9 “(2) DATE SPECIFIED.—The date specified in
10 this paragraph shall be the date that is 1 year from
11 the earlier of—

12 “(A) the estimated completion date of the
13 trial, as submitted under subsection
14 (j)(3)(B)(vi)(I)(hh); or

15 “(B) the actual date of the completion or
16 termination of the trial.

17 “(3) CONDITION OF FEDERAL GRANTS, CON-
18 TRACTS, AND COOPERATIVE AGREEMENTS.—

19 “(A) CERTIFICATION OF COMPLIANCE.—
20 To be eligible to receive a grant, contract, or
21 cooperative agreement from the Secretary for
22 the conduct or support of a clinical trial de-
23 scribed in subsection (j)(3)(B), the principal in-
24 vestigator involved shall certify to the Secretary
25 that—

1 “(i) such investigator shall submit
2 data to the Secretary in accordance with
3 this subsection; and

4 “(ii) such investigator has complied
5 with the requirements of this subsection
6 with respect to other clinical trials con-
7 ducted by such investigator after the date
8 of enactment of the FACT Act.

9 “(B) FAILURE TO SUBMIT CERTIFI-
10 CATION.—An investigator that fails to submit a
11 certification as required under subparagraph
12 (A) shall not be eligible to receive a grant, con-
13 tract, or cooperative agreement from the Sec-
14 retary for the conduct or support of a clinical
15 trial described in subsection (j)(3)(B).

16 “(C) FAILURE TO COMPLY WITH CERTIFI-
17 CATION.—If, by the date specified in paragraph
18 (2), the Secretary has not received the informa-
19 tion or statement described in paragraph (1),
20 the Secretary shall—

21 “(i) transmit to the principal investi-
22 gator involved a notice specifying the infor-
23 mation or statement required to be sub-
24 mitted to the Secretary and stating that
25 such investigator shall not be eligible to re-

1 ceive further funding from the Secretary if
2 such information or statement is not sub-
3 mitted to the Secretary within 30 days of
4 the date on which such notice is trans-
5 mitted; and

6 “(ii) include and prominently display,
7 until such time as the Secretary receives
8 the information or statement described in
9 paragraph (1), as part of the record of
10 such trial in the database described in sub-
11 section (j), a notice stating that the results
12 of such trials have not been reported as re-
13 quired by law.

14 “(D) FAILURE TO COMPLY WITH NO-
15 TICE.—If by the date that is 30 days after the
16 date on which the notice described in subpara-
17 graph (C) is transmitted, the Secretary has not
18 received from the principal investigator involved
19 the information or statement required pursuant
20 to such notice, the Secretary may not award a
21 grant, contract, cooperative agreement, or any
22 other award to such principal investigator until
23 such principal investigator submits to the Sec-
24 retary the information or statement required
25 pursuant to such notice.

1 “(E) SUBMISSION OF STATEMENT BUT
2 NOT INFORMATION.—

3 “(i) IN GENERAL.—If by the date
4 specified in paragraph (2), the Secretary
5 has received a statement described in para-
6 graph (1)(B) but not the information de-
7 scribed in paragraph (1)(A), the Secretary
8 shall transmit to the principal investigator
9 involved a notice stating that such investi-
10 gator shall submit such information by the
11 date determined by the Secretary in con-
12 sultation with such investigator.

13 “(ii) FAILURE TO COMPLY WITH CER-
14 TIFICATION.—If, by the date specified by
15 the Secretary in the notice under clause
16 (i), the Secretary has not received the in-
17 formation described in paragraph (1)(B),
18 the Secretary shall—

19 “(I) transmit to the principal in-
20 vestigator involved a notice specifying
21 the information required to be sub-
22 mitted to the Secretary and stating
23 that such investigator shall not be eli-
24 gible to receive further funding from
25 the Secretary if such information is

1 not submitted to the Secretary within
2 30 days of the date on which such no-
3 tice is transmitted; and

4 “(II) include and prominently
5 display, until such time as the Sec-
6 retary receives the information de-
7 scribed in paragraph (1)(B), as part
8 of the record of such trial in the data-
9 base described in subsection (j), a no-
10 tice stating that the results of such
11 trials have not been reported as re-
12 quired by law.

13 “(F) FAILURE TO COMPLY WITH NO-
14 TICE.—If by the date that is 30 days after the
15 date on which the notice described in subpara-
16 graph (E)(ii)(I) is transmitted, the Secretary
17 has not received from the principal investigator
18 involved the information required pursuant to
19 such notice, the Secretary may not award a
20 grant, contract, cooperative agreement, or any
21 other award to such principal investigator until
22 such principal investigator submits to the Sec-
23 retary the information required pursuant to
24 such notice.

1 “(G) RULE OF CONSTRUCTION.—For pur-
 2 poses of this paragraph, limitations on the
 3 awarding of grants, contracts, cooperative
 4 agreements, or any other awards to principal
 5 investigators for violations of this paragraph
 6 shall not be construed to include any funding
 7 that supports the clinical trial involved.

8 “(4) RULE OF CONSTRUCTION.—Nothing in
 9 this subsection shall be construed to prevent an in-
 10 vestigator other than the investigator described in
 11 paragraph (3)(F) from receiving an ongoing award,
 12 contract, or cooperative agreement.

13 “(5) INCLUSION IN REGISTRY.—

14 “(A) GENERAL RULE.—The Secretary
 15 shall, pursuant to subsection (j)(5), include—

16 “(i) the data described in subsection
 17 (j)(3)(A) and submitted under the amend-
 18 ments made by section 4(a) of the FACT
 19 Act in the registry described in subsection
 20 (j) as soon as practicable after receiving
 21 such data; and

22 “(ii) the data described in clause (I)
 23 of subsection (j)(3)(B)(iv) and submitted
 24 under this subsection or the amendments
 25 made by section 4(a) of the FACT Act in

1 the database described in subsection (j) as
 2 soon as practicable after receiving such
 3 data.

4 “(B) OTHER DATA.—

5 “(i) IN GENERAL.—The Secretary
 6 shall, pursuant to subsection (j)(5), include
 7 the data described in subclauses (II)
 8 through (X) of subsection (j)(3)(B)(iv) and
 9 submitted under this section in the data-
 10 base described in subsection (j)—

11 “(I) as soon as practicable after
 12 receiving such data; or

13 “(II) in the case of data to which
 14 clause (ii) applies, by the date de-
 15 scribed in clause (iii).

16 “(ii) DATA DESCRIBED.—This clause
 17 applies to data described in clause (i) if—

18 “(I) the principal investigator in-
 19 volved requests a delay in the inclu-
 20 sion in the database of such data in
 21 order to have such data published in
 22 a peer reviewed journal; and

23 “(II) the Secretary determines
 24 that an attempt will be made to seek
 25 such publication.

1 “(iii) DATE FOR INCLUSION IN REG-
2 ISTRY.—Subject to clause (iv), the date de-
3 scribed in this clause is the earlier of—

4 “(I) the date on which the data
5 involved is published as provided for
6 in clause (ii); or

7 “(II) the date that is 18 months
8 after the date on which such data is
9 submitted to the Secretary.

10 “(iv) EXTENSION OF DATE.—The
11 Secretary may extend the 18-month period
12 described in clause (iii)(II) for an addi-
13 tional 6 months if the principal investi-
14 gator demonstrates to the Secretary, prior
15 to the expiration of such 18-month period,
16 that the data involved has been accepted
17 for publication by a journal described in
18 clause (ii)(I).

19 “(v) MODIFICATION OF DATA.—Prior
20 to including data in the database under
21 clause (ii) or (iv), the Secretary shall per-
22 mit the principal investigator to modify the
23 data involved.

24 “(6) MEMORANDUM OF UNDERSTANDING.—Not
25 later than 6 months after the date of enactment of

1 the FACT Act, the Secretary shall seek a memo-
 2 randum of understanding with the heads of all other
 3 Federal agencies that conduct clinical trials to in-
 4 clude in the registry and the database clinical trials
 5 sponsored by such agencies that meet the require-
 6 ments of this subsection.

7 “(7) APPLICATION TO CERTAIN PERSONS.—The
 8 provisions of this subsection shall apply to a respon-
 9 sible person described in subsections (p)(1)(A)(ii)(II)
 10 or (p)(1)(B)(i)(II).

11 “(1) TRIALS WITH NON-FEDERAL SUPPORT.—

12 “(1) IN GENERAL.—The responsible person for
 13 a clinical trial described in subsection (j)(3)(B)
 14 shall, not later than the date specified in paragraph
 15 (3), submit to the Secretary—

16 “(A) the information described in sub-
 17 clauses (II) through (X) of subsection
 18 (j)(3)(B)(iv), and with respect to clinical trials
 19 in progress on the date of enactment of the
 20 FACT Act, the information described in sub-
 21 clause (I) of subsection (j)(3)(B)(iv); or

22 “(B) a statement containing information
 23 sufficient to demonstrate to the Secretary that
 24 the information described in subparagraph (A)
 25 cannot reasonably be submitted, along with an

1 estimated date of submission of the information
2 described in such subparagraph.

3 “(2) SANCTION IN CASE OF NONCOMPLIANCE.—

4 “(A) INITIAL NONCOMPLIANCE.—If by the
5 date specified in paragraph (3), the Secretary
6 has not received the information or statement
7 required to be submitted to the Secretary under
8 paragraph (1), the Secretary shall—

9 “(i) transmit to the responsible person
10 for such trial a notice stating that such re-
11 sponsible person shall be liable for the civil
12 monetary penalties described in subpara-
13 graph (B) if the required information or
14 statement is not submitted to the Sec-
15 retary within 30 days of the date on which
16 such notice is transmitted; and

17 “(ii) include and prominently display,
18 until such time as the Secretary receives
19 the information described in paragraph
20 (1), as part of the record of such trial in
21 the database described in subsection (j), a
22 notice stating that the results of such
23 trials have not been reported as required
24 by law.

1 “(B) CIVIL MONETARY PENALTIES FOR
2 NONCOMPLIANCE.—

3 “(i) IN GENERAL.—If by the date that
4 is 30 days after the date on which a notice
5 described in subparagraph (A) is trans-
6 mitted, the Secretary has not received from
7 the responsible person involved the infor-
8 mation or statement required pursuant to
9 such notice, the Secretary shall, after pro-
10 viding the opportunity for a hearing, order
11 such responsible person to pay a civil pen-
12 alty of \$10,000 for each day after such
13 date that the information or statement is
14 not submitted.

15 “(ii) WAIVERS.—In any case in which
16 a responsible person described in clause (i)
17 is a nonprofit entity, the Secretary may
18 waive or reduce the penalties applicable
19 under such clause to such person.

20 “(C) SUBMISSION OF STATEMENT BUT
21 NOT INFORMATION.—

22 “(i) IN GENERAL.—If by the date
23 specified in paragraph (3), the Secretary
24 has received a statement described in para-
25 graph (1)(B) but not the information de-

1 scribed in paragraph (1)(A) the Secretary
2 shall transmit to the responsible person in-
3 volved a notice stating that such respon-
4 sible person shall submit such information
5 by the date determined by the Secretary in
6 consultation with such responsible person.

7 “(ii) FAILURE TO COMPLY.—If, by the
8 date specified by the Secretary in the no-
9 tice under clause (i), the Secretary has not
10 received the information described in para-
11 graph (1)(A), the Secretary shall—

12 “(I) transmit to the responsible
13 person involved a notice specifying the
14 information required to be submitted
15 to the Secretary and stating that such
16 responsible person shall be liable for
17 the civil monetary penalties described
18 in subparagraph (D) if such informa-
19 tion is not submitted to the Secretary
20 within 30 days of the date on which
21 such notice is transmitted; and

22 “(II) include and prominently
23 display, until such time as the Sec-
24 retary receives the information de-
25 scribed in paragraph (1)(A), as part

of the record of such trial in the data-
base described in subsection (j), a no-
tice stating that the results of such
trials have not been reported as re-
quired by law.

“(D) NONCOMPLIANCE.—

“(i) IN GENERAL.—If by the date that
is 30 days after the date on which a notice
described in subparagraph (C)(ii)(I) is
transmitted, the Secretary has not received
from the responsible person involved the
information required pursuant to such no-
tice, the Secretary, after providing the op-
portunity for a hearing, order such respon-
sible person to pay a civil penalty of
\$10,000 for each day after such date that
the information is not submitted.

“(ii) WAIVERS.—In any case in which
a responsible person described in clause (i)
is a nonprofit entity, the Secretary may
waive or reduce the penalties applicable
under such clause to such person.

“(E) NOTICE OF PUBLICATION OF DATA.—

If the responsible person is the manufacturer or
distributor of the drug, biological product, or

1 device involved, the notice under subparagraphs
2 (A)(i) and (C)(ii)(I) shall include a notice that
3 the Secretary shall publish the data described
4 in subsection (j)(3)(B) in the database if the re-
5 sponsible person has not submitted the informa-
6 tion specified in the notice transmitted by the
7 date that is 6 months after the date of such no-
8 tice.

9 “(F) PUBLICATION OF DATA.—Notwith-
10 standing section 301(j) of the Federal Food,
11 Drug, and Cosmetic Act, section 1905 of title
12 18, United States Code, or any other provision
13 of law, if the responsible person is the manufac-
14 turer or distributor of the drug, biological prod-
15 uct, or device involved, and if the responsible
16 person has not submitted to the Secretary the
17 information specified in a notice transmitted
18 pursuant to subparagraph (A)(i) or (C)(ii)(I) by
19 the date that is 6 months after the date of such
20 notice, the Secretary shall publish in the reg-
21 istry information that—

22 “(i) is described in subsection
23 (j)(3)(B); and

24 “(ii) the responsible person has sub-
25 mitted to the Secretary in any application,

1 including a supplemental application, for
2 the drug or device under section 505, 510,
3 515, or 520 of the Federal Food, Drug,
4 and Cosmetic Act or for the biological
5 product under section 351.

6 “(3) DATE SPECIFIED.—The date specified in
7 this paragraph shall be the date that is 1 year from
8 the earlier of—

9 “(A) the estimated completion date of the
10 trial, submitted under subsection
11 (j)(3)(B)(vi)(I)(hh); or

12 “(B) the actual date of completion or ter-
13 mination of the trial.

14 “(4) USE OF FUNDS.—

15 “(A) IN GENERAL.—The Secretary shall
16 deposit the funds collected under paragraph (2)
17 into an account and use such funds, in con-
18 sultation with the Director of the Agency for
19 Healthcare Research and Quality, to fund stud-
20 ies that compare the clinical effectiveness of 2
21 or more treatments for a disease or condition.

22 “(B) FUNDING DECISIONS.—The Secretary
23 shall award funding under subparagraph (A)
24 based on a priority list established not later
25 than 6 months after the date of enactment of

the FACT Act by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

“(5) INCLUSION IN REGISTRY.—

“(A) GENERAL RULE.—The Secretary shall, pursuant to subsection (j)(5), include—

“(i) the data described in subsection (j)(3)(A) and submitted under the amendments made by section 4(a) of the FACT Act in the registry described in subsection (j) as soon as practicable after receiving such data; and

“(ii) the data described in clause (I) of subsection (j)(3)(B)(iv) and submitted under this subsection in the database described in subsection (j) as soon as practicable after receiving such data.

“(B) OTHER DATA.—

“(i) IN GENERAL.—The Secretary shall, pursuant to subsection (j)(5), include the data described in subclauses (II) through (X) of subsection (j)(3)(B)(iv) and submitted under this section in the database described in subsection (j)—

1 “(I) as soon as practicable after
2 receiving such data; or

3 “(II) in the case of data to which
4 clause (ii) applies, by the date de-
5 scribed in clause (iii).

6 “(ii) DATA DESCRIBED.—This clause
7 applies to data described in clause (i) if—

8 “(I) the responsible person in-
9 volved requests a delay in the inclu-
10 sion in the database of such data in
11 order to have such data published in
12 a peer reviewed journal; and

13 “(II) the Secretary determines
14 that an attempt will be made to seek
15 such publication.

16 “(iii) DATE FOR INCLUSION IN REG-
17 ISTRY.—Subject to clause (iv), the date de-
18 scribed in this clause is the earlier of—

19 “(I) the date on which the data
20 involved is published as provided for
21 in clause (ii); or

22 “(II) the date that is 18 months
23 after the date on which such data is
24 submitted to the Secretary.

1 “(iv) EXTENSION OF DATE.—The
2 Secretary may extend the 18-month period
3 described in clause (iii)(II) for an addi-
4 tional 6 months if the responsible person
5 demonstrates to the Secretary, prior to the
6 expiration of such 18-month period, that
7 the data involved has been accepted for
8 publication by a journal described in clause
9 (ii)(I).

10 “(v) MODIFICATION OF DATA.—Prior
11 to including data in the database under
12 clause (ii) or (iv), the Secretary shall per-
13 mit the responsible person to modify the
14 data involved.

15 “(6) EFFECT.—The information with respect to
16 a clinical trial submitted to the Secretary under this
17 subsection, including data published by the Sec-
18 retary pursuant to paragraph (2)(F), may not be
19 submitted by a person other than the responsible
20 person as part of, or referred to in, an application
21 for approval of a drug or device under section 505,
22 510, 515, or 520 of the Federal Food, Drug, and
23 Cosmetic Act or of a biological product under section
24 351, unless the information is available from a

1 source other than the registry or database described
2 in subsection (j).

3 “(m) PROCEDURES AND WAIVERS.—

4 “(1) SUBMISSION PRIOR TO NOTICE.—Nothing
5 in subsections (k) through (l) shall be construed to
6 prevent a principal investigator or a responsible per-
7 son from submitting any information required under
8 this subsection to the Secretary prior to receiving
9 any notice described in such subsections.

10 “(2) ONGOING TRIALS.—A factually accurate
11 statement that a clinical trial is ongoing shall be
12 deemed to be information sufficient to demonstrate
13 to the Secretary that the information described in
14 subsections (k)(1)(A) and (l)(1)(A) cannot reason-
15 ably be submitted.

16 “(3) INFORMATION PREVIOUSLY SUBMITTED.—
17 Nothing in subsections (k) through (l) shall be con-
18 strued to require the Secretary to send a notice to
19 any principal investigator or responsible person re-
20 quiring the submission to the Secretary of informa-
21 tion that has already been submitted.

22 “(4) SUBMISSION FORMAT AND TECHNICAL
23 STANDARDS.—

24 “(A) IN GENERAL.—The Secretary shall,
25 to the extent practicable, accept submissions re-

1 quired under this subsection in an electronic
2 format and shall establish interoperable tech-
3 nical standards for such submissions.

4 “(B) CONSISTENCY OF STANDARDS.—To
5 the extent practicable, the standards established
6 under subparagraph (A) shall be consistent
7 with standards adopted by the Consolidated
8 Health Informatics Initiative (or a successor or-
9 ganization to such Initiative) to the extent such
10 Initiative (or successor) is in operation.

11 “(5) TRIALS COMPLETED PRIOR TO ENACT-
12 MENT.—The Secretary shall establish procedures
13 and mechanisms to allow for the voluntary submis-
14 sion to the database of the information described in
15 subsection (j)(3)(B) with respect to clinical trials
16 completed prior to the date of enactment of the
17 FACT Act. In cases in which it is in the interest of
18 public health, the Secretary may require that infor-
19 mation from such trials be submitted to the data-
20 base. Failure to comply with such a requirement
21 shall be deemed to be a failure to submit informa-
22 tion as required under this section, and the appro-
23 priate remedies and sanctions under this section
24 shall apply.

1 “(6) TRIALS NOT INVOLVING DRUGS, BIOLOGI-
2 CAL PRODUCTS, OR DEVICES.—The Secretary shall
3 establish procedures and mechanisms to allow for
4 the voluntary submission to the database of the in-
5 formation described in subsection (j)(3)(B) with re-
6 spect to clinical trials that do not involve drugs, bio-
7 logical products, or devices. In cases in which it is
8 in the interest of public health, the Secretary may
9 require that information from such trials be sub-
10 mitted to the database. Failure to comply with such
11 a requirement shall be deemed to be a failure to sub-
12 mit information as required under this section, and
13 the appropriate remedies and sanctions under this
14 section shall apply.

15 “(7) SUBMISSION OF INACCURATE INFORMA-
16 TION.—

17 “(A) IN GENERAL.—If the Secretary deter-
18 mines that information submitted by a principal
19 investigator or a responsible person under this
20 section is factually and substantively inaccurate,
21 the Secretary shall submit a notice to the inves-
22 tigator or responsible person concerning such
23 inaccuracy that includes—

24 “(i) a summary of the inaccuracies in-
25 volved; and

1 “(ii) a request for corrected informa-
2 tion within 30 days.

3 “(B) AUDIT OF INFORMATION.—

4 “(i) IN GENERAL.—The Secretary
5 may conduct audits of any information
6 submitted under subsection (j).

7 “(ii) REQUIREMENT.—Any principal
8 investigator or responsible person that has
9 submitted information under subsection (j)
10 shall permit the Secretary to conduct the
11 audit described in clause (i).

12 “(C) CHANGES TO INFORMATION.—Any
13 change in the information submitted by a prin-
14 cipal investigator or a responsible person under
15 this section shall be reported to the Secretary
16 within 30 days of the date on which such inves-
17 tigator or person became aware of the change
18 for purposes of updating the registry or the
19 database.

20 “(D) FAILURE TO CORRECT.—If a prin-
21 cipal investigator or a responsible person fails
22 to permit an audit under subparagraph (B),
23 provide corrected information pursuant to a no-
24 tice under subparagraph (A), or provide
25 changed information under subparagraph (C),

1 the investigator or responsible person involved
 2 shall be deemed to have failed to submit infor-
 3 mation as required under this section and the
 4 appropriate remedies and sanction under this
 5 section shall apply.

6 “(E) CORRECTIONS.—

7 “(i) IN GENERAL.—The Secretary
 8 may correct, through any means deemed
 9 appropriate by the Secretary to protect
 10 public health, any information included in
 11 the registry or the database described in
 12 subsection (j) (including information de-
 13 scribed or contained in a publication re-
 14 ferred to under subclause (VI) of sub-
 15 section (j)(3)(B)(iv)) that is—

16 “(I) submitted to the Secretary
 17 for inclusion in the registry or the
 18 database; and

19 “(II) factually and substantively
 20 inaccurate or false or misleading.

21 “(ii) RELIANCE ON INFORMATION.—

22 The Secretary may rely on any information
 23 from a clinical trial or a report of an ad-
 24 verse event acquired or produced under the
 25 authority of section 351 of this Act or of

the Federal Food, Drug, and Cosmetic Act
in determining whether to make correc-
tions as provided for in clause (i).

“(iii) DETERMINATIONS RELATING TO
MISLEADING INFORMATION.—For purposes
of clause (i)(II), in determining whether
information is misleading, the Secretary
shall use the standard described in section
201(n) of the Federal Food, Drug, and
Cosmetic Act that is used to determine
whether labeling or advertising is mis-
leading.

“(iv) RULE OF CONSTRUCTION.—This
subparagraph shall not be construed to au-
thorize the disclosure of information if—

“(I) such disclosure would con-
stitute an invasion of personal pri-
vacy;

“(II) such information concerns a
method or process which as a trade
secret is entitled to protection within
the meaning of section 301(j) of the
Federal Food, Drug, and Cosmetic
Act;

1 “(III) such disclosure would dis-
2 close confidential commercial informa-
3 tion or a trade secret, other than a
4 trade secret described in subclause
5 (II), unless such disclosure is nec-
6 essary—

7 “(aa) to make a correction
8 as provided for under clause (i);
9 and

10 “(bb) protect the public
11 health; or

12 “(IV) if such disclosure relates to
13 a biological product for which no li-
14 cense is in effect under section 351, a
15 drug for which no approved applica-
16 tion is in effect under section 505(c)
17 of the Federal Food, Drug, and Cos-
18 metic Act, or a device that is not
19 cleared under section 510(k) of such
20 Act or for which no application is in
21 effect under section 515 of such Act.

22 “(v) NOTICE.—In the case of a disclo-
23 sure under clause (iv)(III), the Secretary
24 shall notify the manufacturer or distributor

1 of the drug, biological product, or device
 2 involved—

3 “(I) at least 30 days prior to
 4 such disclosure; or

5 “(II) if immediate disclosure is
 6 necessary to protect the public health,
 7 concurrently with such disclosure.

8 “(8) WAIVERS REGARDING CLINICAL TRIAL RE-
 9 SULTS.—The Secretary may waive the requirements
 10 of subsections (k)(1) and (l)(1) that the results of
 11 clinical trials be submitted to the Secretary, upon a
 12 written request from the responsible person if the
 13 Secretary determines that extraordinary cir-
 14 cumstances justify the waiver and that providing the
 15 waiver is in the public interest or consistent with the
 16 protection of public health.

17 “(n) TRIALS CONDUCTED OUTSIDE OF THE UNITED
 18 STATES.—

19 “(1) IN GENERAL.—With respect to clinical
 20 trials described in paragraph (2), the responsible
 21 person shall submit to the Secretary the information
 22 required under subclauses (II) through (X) of sub-
 23 section (j)(3)(B)(iv). Failure to comply with this
 24 paragraph shall be deemed to be a failure to submit
 25 information as required under this section, and the

1 appropriate remedies and sanctions under this sec-
 2 tion shall apply.

3 “(2) CLINICAL TRIAL DESCRIBED.—A clinical
 4 trial is described in this paragraph if—

5 “(A) such trial is conducted outside of the
 6 United States; and

7 “(B) the data from such trial is—

8 “(i) submitted to the Secretary as
 9 part of an application, including a supple-
 10 mental application, for a drug or device
 11 under section 505, 510, 515, or 520 of the
 12 Federal Food, Drug, and Cosmetic Act or
 13 for the biological product under section
 14 351; or

15 “(ii) used in advertising or labeling to
 16 make a claim about the drug, device, or bi-
 17 ological product involved.

18 “(o) DEFINITIONS; INDIVIDUAL LIABILITY.—

19 “(1) RESPONSIBLE PERSON.—

20 “(A) IN GENERAL.—In this section, the
 21 term ‘responsible person’ with respect to a clin-
 22 ical trial, means—

23 “(i) if such clinical trial is the subject
 24 of an investigational new drug application
 25 or an application for an investigational de-

1 vice exemption, the sponsor of such inves-
 2 tigational new drug application or such ap-
 3 plication for an investigational device ex-
 4 emption; or

5 “(ii) except as provided in subpara-
 6 graph (B), if such clinical trial is not the
 7 subject of an investigational new drug ap-
 8 plication or an application for an investiga-
 9 tional device exemption—

10 “(I) the person that provides the
 11 largest share of the monetary support
 12 (such term does not include in-kind
 13 support) for the conduct of such trial;
 14 or

15 “(II) in the case in which the
 16 person described in subclause (I) is a
 17 Federal or State agency, the principal
 18 investigator of such trial.

19 “(B) NONPROFIT ENTITIES AND REQUEST-
 20 ING PERSONS.—

21 “(i) NONPROFIT ENTITIES.—For pur-
 22 poses of subparagraph (A)(ii)(I), if the
 23 person that provides the largest share of
 24 the monetary support for the conduct of
 25 the clinical trial involved is a nonprofit en-

1 tity, the responsible person for purposes of
2 this section shall be—

3 “(I) the nonprofit entity; or

4 “(II) if the nonprofit entity and
5 the principal investigator of such trial
6 jointly certify to the Secretary that
7 the principal investigator will be re-
8 sponsible for submitting the informa-
9 tion described in subsection (j)(3)(B)
10 for such trial, the principal investi-
11 gator.

12 “(ii) REQUESTING PERSONS.—For
13 purposes of subparagraph (A)(ii)(I), if a
14 person—

15 “(I) has submitted a request to
16 the Secretary that the Secretary rec-
17 ognize the person as the responsible
18 person for purposes of this section;
19 and

20 “(II) the Secretary determines
21 that such person—

22 “(aa) provides monetary
23 support for the conduct of such
24 trial;

1 “(bb) is responsible for the
2 conduct of such trial; and

3 “(cc) will be responsible for
4 submitting the information de-
5 scribed in subsection (j)(3)(B)
6 for such trial;

7 such person shall be the responsible person
8 for purposes of this section.

9 “(2) DRUG, DEVICE, BIOLOGICAL PRODUCT.—

10 In this section—

11 “(A) the terms ‘drug’ and ‘device’ have the
12 meanings given such terms in section 201 of
13 the Federal Food, Drug, and Cosmetic Act; and

14 “(B) the term ‘biological product’ has the
15 meaning given such term in section 351 of this
16 Act.

17 “(3) INDIVIDUAL LIABILITY.—

18 “(A) LIMITATION ON LIABILITY OF INDIVIDUALS.—No individual shall be liable for any
19 civil monetary penalty under this section.

21 “(B) INDIVIDUALS WHO ARE RESPONSIBLE
22 PERSONS.—If a responsible person under sub-
23 paragraph (A) or (B) of paragraph (1) is an
24 individual, such individual shall be subject to

1 the procedures and conditions described in sub-
2 section (k).”.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
4 402 of the Public Health Service Act (42 U.S.C. 282),
5 as amended by this section, is further amended by adding
6 at the end the following:

7 “(s) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated, such sums as may be
9 necessary to carry out this section.”.

10 **SEC. 4. REVIEW AND APPROVAL OF PROPOSALS FOR RE-**
11 **SEARCH.**

12 (a) AMENDMENTS.—Section 492A(a) of the Public
13 Health Service Act (42 U.S.C. 289a–1(a)) is amended—

14 (1) in paragraph (1)(A), by striking “unless”
15 and all that follows through the period and inserting
16 the following: “unless—

17 “(i) the application has undergone re-
18 view in accordance with such section and
19 has been recommended for approval by a
20 majority of the members of the Board con-
21 ducting the review;

22 “(ii) such Board has submitted to the
23 Secretary a notification of such approval;
24 and

1 “(iii) with respect to an application
 2 involving a clinical trial to which section
 3 402(j) applies, the principal investigator
 4 who has submitted such application has
 5 submitted to the Secretary for inclusion in
 6 the registry and the database described in
 7 section 402(j) the information described in
 8 paragraph (3)(A) and subclause (I) of
 9 paragraph (3)(B)(iv) of such section.”; and
 10 (2) by adding at the end the following:

11 “(3) COST RECOVERY.—Nonprofit entities may
 12 recover the full costs associated with compliance
 13 with the requirements of paragraph (1) from the
 14 Secretary as a direct cost of research.”.

15 (b) REGULATIONS.—The Secretary of Health and
 16 Human Services shall modify the regulations promulgated
 17 at part 46 of title 45, Code of Federal Regulations, part
 18 50 of title 21, Code of Federal Regulations, and part 56
 19 of title 21, Code of Federal Regulations, to reflect the
 20 amendments made by subsection (a).

21 **SEC. 5. PROHIBITED ACTS.**

22 Section 301 of the Federal Food, Drug, and Cosmetic
 23 Act (21 U.S.C. 331) is amended by adding at the end the
 24 following:

1 “(hh)(1) The entering into of a contract or other
2 agreement by a responsible person or a manufacturer of
3 a drug, biological product, or device with an individual
4 who is not an employee of such responsible person or man-
5 ufacturer, or the performance of any other act by such
6 a responsible person or manufacturer, that prohibits, lim-
7 its, or imposes unreasonable delays on the ability of such
8 individual to—

9 “(A) discuss the results of a clinical trial at a
10 scientific meeting or any other public or private
11 forum; or

12 “(B) publish the results of a clinical trial or a
13 description or discussion of the results of a clinical
14 trial in a scientific journal or any other publication.

15 “(2) The entering into a contract or other agreement
16 by a responsible person or a manufacturer of a drug, bio-
17 logical product, or device with an academic institution or
18 a health care facility, or the performance of any other act
19 by such a responsible person or manufacturer, that pro-
20 hibits, limits, or imposes unreasonable delays on the abil-
21 ity of an individual who is not an employee of such respon-
22 sible person or manufacturer to—

23 “(A) discuss the results of a clinical trial at a
24 scientific meeting or any other public or private
25 forum; or

1 “(B) publish the results of a clinical trial or a
 2 description or discussion of the results of a clinical
 3 trial in a scientific journal or any other publica-
 4 tion.”.

5 **SEC. 6. REPORTS.**

6 (a) IMPLEMENTATION REPORT.—Not later than 1
 7 year after the date of enactment of this Act, the Secretary
 8 of Health and Human Services shall submit to the appro-
 9 priate committees of Congress a report on the status of
 10 the implementation of the requirements of the amend-
 11 ments made by section 3 that includes a description of
 12 the number and types of clinical trials for which informa-
 13 tion has been submitted under such amendments.

14 (b) DATA COLLECTION.—

15 (1) IN GENERAL.—The Secretary of Health and
 16 Human Services shall enter into a contract with the
 17 Institute of Medicine for the conduct of a study con-
 18 cerning the extent to which data submitted to the
 19 registry under section 402(j) of the Public Health
 20 Service Act (42 U.S.C. 282(j)) has impacted the
 21 public health.

22 (2) REPORT.—Not later than 6 months after
 23 the date on which a contract is entered into under
 24 paragraph (1), the Institute of Medicine shall submit
 25 to the Secretary of Health and Human Services a

1 report on the results of the study conducted under
2 such paragraph. Such report shall include rec-
3 ommendations for changes to the registry, the data-
4 base, and the data submission requirements that
5 would benefit the public health.

○